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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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1633

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|---------------------------------------|--|
| Office Action Summary | Application No. 10/821,568 | Applicant(s) REMACLE ET AL. | |
| | Examiner Fereydoun G. Sajjadi | Art Unit 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-35 are pending in this application.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, 11-20, and 21-26, drawn to a screening and/or quantification method of one or more activated transcriptional factor(s), said method comprising binding double stranded DNA sequence(s) to an insoluble solid support by covalent binding, classifiable in class 435, subclass 6.
 - II. Claims 1-8, 10-20, and 21-26, drawn to a screening and/or quantification method of one or more activated transcriptional factor(s), said method comprising binding double stranded DNA sequence(s) to an insoluble solid support by non-covalent binding, classifiable in class 435, subclass 6.
 - III. Claims 27-35, drawn to a kit for screening and/or quantification of one or more activated transcriptional factor(s), comprising binding double stranded DNA sequence(s) to an insoluble solid support by covalent binding, classifiable in class 435, subclass 6.
 - IV. Claims 27-33, and 35, drawn to a kit for screening and/or quantification of one or more activated transcriptional factor(s), comprising binding double stranded DNA sequence(s) to an insoluble solid support by non-covalent binding, classifiable in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Restriction is deemed to be proper because these methods constitute patentably distinct inventions they are not disclosed as capable of use together or they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Inventions I-II are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of inventions I and II are each distinct from the other, because invention I requires covalent binding of double stranded DNA sequences to a solid support, whereas the nature of binding to the solid support of invention of II is non-

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covalent. Thus, the methods are distinct. Each method is directed to a distinct goal or a materially distinct step, is capable of separate use and employs particulars not commonly shared. Hence, the search and examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination.

Inventions III and IV are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, Inventions III and IV are each distinct from the other, because invention III requires covalent binding of double stranded DNA sequences to a solid support, whereas the nature of binding to the solid support of inventions of IV is non-covalent. Each method is directed to a distinct goal or a materially distinct step, is capable of separate use and employs particulars not commonly shared. Hence, the search and examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination.

Inventions III-IV and I-II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the kit of inventions III and IV may be used to detect the binding of DNA binding proteins that are not transcription factors or compounds that bind or modulate transcription factors. Therefore inventions I-II and III-IV are distinct, each from the other.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper

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restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper. The combined search and examination of the different products and methods of the inventions in Groups I-IV, would not be coextensive and would impose a serious burden on the examiner (see MPEP § 808.02).

3. This application contains claims directed to the following groups of patentably distinct species of the claimed invention:

For Groups I and II – Applicant is required to choose a specific binding pair, as recited in claim 11. The biotin/streptavidin, hapten/receptor, and antigen/antibody are each structurally and functionally distinct and further capable of separate utility, the search and examination of their respective subject matter is not coextensive and imposes an undue burden on the examiner.

For Groups I and II – Applicant is required to choose a specific transcription factor, as recited in claim 16 and table 1. The NF-KB, AP-1, CREB, SP-1, etc., are each structurally and functionally distinct and further capable of separate utility. The search and examination of their respective subject matter is non-coextensive and imposes an undue burden on the examiner.

Applicant is required under 35 U.S.C. §121 to elect a single disclosed species for each of the groups above, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims, 1-19, and 21-35 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, and/or because of the patentably distinct species are listed above, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response for this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst William Phillips, whose telephone number is **(571) 272-0548**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is **(571) 272-3311**. The examiner can normally be reached Monday through Friday, between 7:00 am-4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on **(571) 272-0731**. The fax phone number for the organization where this application or proceeding is assigned is **(571) 273-8300**. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at **(800) 786-9199**.

Fereydoun G. Sajjadi, Ph.D.
Examiner, USPTO, AU 1633



ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

